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10/510,942	10/08/2004	Bruce K. Jankowski	2780(203-3093)	7109

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EXAMINER	
CHEN, VICTORIA W	

ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,942	JANKOWSKI, BRUCE K.	
	Examiner	Art Unit	
	VICTORIA W. CHEN	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 15-19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Turkel et al. (US 5792074).

Regarding claim 1, Turkel discloses a surgical instrument [18 and 12] for performing a surgical procedure, an instrument introducer assembly including a tubular body portion [22] defining a lumen [20] therethrough, the tubular body portion having a proximal and distal end [Fig. 1], a distal end portion [24] secured to the distal end of the tubular body portion, the distal end portion defining a pocket [Fig. 2a] having an annular wall [Fig. 3, portion of pocket wall in contact with 18] with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument [18, Fig. 3] along substantially the length of the pocket, and including a substantially planar distal end wall [24, Fig. 2] configured to stretch and conform to a shape of the outer surface of the surgical instrument [outer surface of 18, Fig. 3] to facilitate passage of the surgical instrument in a sealing relation [col. 8, ll. 64-67] to the surgical instrument, wherein the surgical instrument stretches the distal end portion of the instrument introducer as it is advanced therethrough [col. 4, ll. 65-67, col. 5, ll. 1-5].

Regarding claim 2, Turkel discloses the distal end portion includes an annular side wall [corresponding part of element 24 where 22a is labeled in Fig. 2a] depending from an outer terminal edge thereof [Fig. 2a].

Regarding claim 3, Turkel discloses the distal end portion is made from an elastomeric material [col. 4, ll. 14-15].

Regarding claim 4, Turkel discloses the distal end wall includes an aperture [26].

Regarding claim 5, Turkel discloses the aperture is coaxially aligned with a central longitudinal axis of the tubular body portion [Fig. 2].

Regarding claims 6 and 7, Turkel discloses the distal end portion is secured to the distal end of the tubular body portion such that the annular side wall is capable of at least partially overlapping and completely overlapping the distal end of the tubular body portion [Fig. 2a].

Regarding claim 8, Turkel discloses a proximal terminal edge of the annular side wall of the distal end portion [24] is secured to a distal terminal edge [22a] of the distal end of the tubular body [22] [Fig. 2a].

Regarding claim 9, Turkel discloses the distal end portion is secured to the distal end of the tubular body by gluing [col. 4, ll. 52-54].

Regarding claim 10, Turkel discloses the tubular body portion is fabricated from polypropylene [col. 4, ll. 39-42].

Regarding claim 11, Turkel discloses a flange [32] extending from the proximal end of the tubular body portion.

Regarding claim 12, Turkel discloses the distal end wall of the distal end portion is provided with a region of weakened strength [26].

Regarding claim 13, Turkel discloses the region of weakened strength includes either score lines or reduced thickness [co. 4, ll. 52-64].

Regarding claim 15, Turkel discloses a surgical instrument for performing a surgical procedure [18 and 12], an instrument introducer assembly including a hollow elongate cylindrical body [22] including a distal end portion [Fig. 2a] terminating in a distal edge [Fig. 2a, labeled 22a] and a proximal end portion [32], the cylindrical body defining a central longitudinal axis, an elastomeric cap [24] secured to the distal end portion of the cylindrical body [Fig. 2a], the cap defining a pocket [Fig. 2a] having an annular wall [Fig. 3, portion of pocket wall in contact with 18] with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument [18, Fig. 3] along substantially the length of the pocket, and including a substantially planar distal end wall [24, Fig. 2a] having an outer terminal edge [Fig. 2a, edge of 24 corresponding to element labeled as 22a], the distal end wall including an aperture [26] formed within the pocket [Fig. 2a] configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument [outer surface of 18] to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument [col. 8, ll. 64-67], wherein a center of the aperture is coaxially aligned with the central longitudinal axis [Fig. 2a], wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough [col. 4, ll. 65-67, col. 5, ll. 1-5].

Regarding claim 16, Turkel discloses the cylindrical body is configured to receive a surgical instrument there through [Fig. 3].

Regarding claim 17, Turkel discloses a flange [32] extending outward from a proximal terminal edge of the proximal end portion of the cylindrical body.

Regarding claim 18, Turkel discloses the cap [24] is secured to the distal end of the cylindrical body such that the distal end wall of the cap is spaced a distance from the distal terminal edge of the cylindrical body [Fig. 2a].

Regarding claim 19, Turkel discloses the cap [24] is secured to the distal end of the cylindrical body such that a proximal terminal edge of the annular side wall is secured to the distal terminal edge [22a] of the cylindrical body [Fig. 2a].

Regarding claim 23, Turkel discloses a surgical instrument [18 and 12] for performing a surgical procedure, an instrument introducer assembly including a tubular body portion [22] defining a lumen [20] therethrough, the tubular body portion having a proximal [32] and distal end [22a], a distal end portion [24] secured to the distal end of the tubular body portion, the distal end portion defining a pocket [Fig. 2a] and including a substantially circular distal end wall [wall in Fig. 3 at point labeled 24] having a diameter smaller than a diameter of the tubular body portion [diameter of circular distal end wall being the diameter in Fig. 3 where label 24 touches, which is smaller than the diameter of the tubular body portion where label 22 is located], and an annular wall [Fig. 3, portion of pocket wall in contact with 18, labeled 26a] depending from the circular distal end wall to the tubular body portion, wherein the annular wall is adapted to contact an outer surface of a surgical instrument [Fig. 3], wherein the distal end wall of the distal end portion includes an aperture [26] formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument in a sealing relation [col. 8, ll. 64-67] to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough [col. 4, ll. 65-67, col. 5, ll. 1-5],

and further where the aperture has a smaller diameter than a diameter of the circular distal end wall [Fig. 2a], and wherein the aperture is provided with a region of weakened strength [26].

Claims 1-9, 11, 12, 15-19 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 5752970).

Regarding claim 1, Yoon discloses a surgical instrument [38] for performing a surgical procedure, an instrument introducer assembly including a tubular body portion [104] defining a lumen [114, Fig. 15] therethrough, the tubular body portion having a proximal and distal end [Fig. 15], a distal end portion [116] secured to the distal end of the tubular body portion, the distal end portion defining a pocket [interior of 116] having an annular wall [Fig. 15] with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument [Fig. 3] along substantially the length of the pocket, and including a substantially planar distal end wall [Fig. 15] configured to stretch and conform to a shape of the outer surface of the surgical instrument [Fig. 3] to facilitate passage of the surgical instrument in a sealing relation [col. 2, ll. 10-12] to the surgical instrument, wherein the surgical instrument stretches the distal end portion of the instrument introducer as it is advanced therethrough [col. 4, ll. 6-11].

Regarding claim 2, Yoon discloses the distal end portion includes an annular side wall [Fig. 15] depending from an outer terminal edge thereof.

Regarding claim 3, Yoon discloses the distal end portion is made from an elastomeric material [col. 4, ll. 6-11].

Regarding claim 4, Yoon discloses the distal end wall includes an aperture [Fig. 3].

Regarding claim 5, Yoon discloses the aperture is coaxially aligned with a central longitudinal axis of the tubular body portion [Fig. 15].

Regarding claims 6 and 7, Yoon discloses the distal end portion is secured to the distal end of the tubular body portion such that the annular side wall is capable of at least partially overlapping and completely overlapping the distal end of the tubular body portion [Fig. 15, overlap of 122 and 114].

Regarding claim 8, Yoon discloses a proximal terminal edge of the annular side wall of the distal end portion [122] is secured to a distal terminal edge [114] of the distal end of the tubular body [Fig. 15].

Regarding claim 9, Yoon discloses the distal end portion is secured to the distal end of the tubular body by bonding [col. 8, ll. 1-2].

Regarding claim 11, Yoon discloses a flange [118] extending from the proximal end of the tubular body portion.

Regarding claim 12, Yoon discloses the distal end wall of the distal end portion is provided with a region of weakened strength [26].

Regarding claim 15, Yoon discloses a surgical instrument for performing a surgical procedure [38], an instrument introducer assembly including a hollow elongate cylindrical body [104] including a distal end portion terminating in a distal edge [114] and a proximal end portion, the cylindrical body defining a central longitudinal axis, an elastomeric cap [116] secured to the distal end portion of the cylindrical body [Fig. 15], the cap defining a pocket [Fig. 15] having an annular wall [Fig. 3, portion of pocket wall in contact with 38] with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the

surgical instrument [Fig. 3] along substantially the length of the pocket, and including a substantially planar distal end wall [26] having an outer terminal edge, the distal end wall including an aperture [26] formed within the pocket configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument [outer surface of 18] to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument [col. 2, ll. 10-12], wherein a center of the aperture is coaxially aligned with the central longitudinal axis [Fig. 15], wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough [col. 4, ll. 6-11].

Regarding claim 16, Yoon discloses the cylindrical body is configured to receive a surgical instrument there through [Fig. 3].

Regarding claim 17, Yoon discloses a flange [118] extending outward from a proximal terminal edge of the proximal end portion of the cylindrical body.

Regarding claim 18, Yoon discloses the cap [116] is secured to the distal end of the cylindrical body such that the distal end wall of the cap is spaced a distance from the distal terminal edge of the cylindrical body [Fig. 15].

Regarding claim 19, Yoon discloses the cap [116] is secured to the distal end of the cylindrical body such that a proximal terminal edge [122] of the annular side wall is secured to the distal terminal edge [114] of the cylindrical body [Fig. 15].

Regarding claim 21, Yoon discloses providing a surgical instrument [38] for performing a surgical procedure, providing an instrument introducer assembly [Fig. 15] including a hollow tubular body [104] having a distal end portion [Fig. 15] and proximal end portion, defining a lumen [Fig. 15, 114] therebetween, and a resilient cap [116] secured to the distal end of the

tubular body, the cap defining a pocket [inside of 116] having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of a surgical instrument [Fig. 3] along substantially the length of the pocket, and including a substantially planar distal end wall [Fig. 15] having an aperture [26] formed therein, inserting the distal end of the instrument introducer into a body cavity [Fig. 4], inserting the surgical instrument [Fig. 4] into the lumen of the tubular body of the instrument introducer through a proximal end of the tubular body, advancing the surgical instrument through the lumen of the tubular body of the instrument introducer thereby stretching the instrument introducer [col. 4, ll. 43-58] such that the aperture of the distal end wall stretches and conforms to a shape of the outer surface of the surgical instrument until a distal end of the surgical instrument projects out through the aperture of the cap, wherein the cap creates a seal around the perimeter the surgical instrument [col. 2, ll. 10-12].

Regarding claim 22, see rejection of claim 21.

Regarding claim 23, Yoon discloses a surgical instrument [38] for performing a surgical procedure, an instrument introducer assembly including a tubular body portion [104] defining a lumen [Fig. 15] therethrough, the tubular body portion having a proximal [118] and distal end, a distal end portion [116] secured to the distal end of the tubular body portion, the distal end portion defining a pocket [interior of 116] and including a substantially circular distal end wall [Fig. 15] having a diameter smaller than a diameter of the tubular body portion [diameter of 116, which is smaller than the diameter of the tubular body portion where label 118 is located], and an annular wall [116] depending from the circular distal end wall to the tubular body portion, wherein the annular wall is adapted to contact an outer surface of a surgical instrument [Fig. 3],

wherein the distal end wall of the distal end portion includes an aperture [26] formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument in a sealing relation [col. 2, ll. 10-12] to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough [col. 4, ll. 43-58], and further where the aperture has a smaller diameter than a diameter of the circular distal end wall [Fig. 3a], and wherein the aperture is provided with a region of weakened strength [26].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 5752970), as applied to claim 4 above, in view of Mollenauer et al. (US 5634937).

Yoon teaches the invention as claimed, including the tubular body being fabricated from medically acceptable plastic materials [col. 3, ll. 49-51], but fails to specifically teach polypropylene. Mollenauer teaches an instrument introducer body [10] for introducing instruments into a body lumen wherein the introducer body is fabricated from polypropylene [col. 6, ll. 45-49] since it is a commonly known biocompatible material. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the tubular body from polypropylene since it is commonly known in the art as a biocompatible material used to form medical devices.

Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 5752970), as applied to claim 4 and 15 above, in view of Staskin et al. (US 2002/0099258 A1).

Regarding claims 14 and 20, Yoon teaches the invention as claimed, but fails to specifically teach the distal end portion having a frustoconical profile including a concave annular side wall. Staskin teaches an introducer [54] having an aperture [96] at the distal end wherein the distal end of the introducer has a frustoconical profile including a concave annular side wall [Fig. 10C] in order to cam tissue out of the path of insertion and to reduce the amount of friction during insertion, thereby reducing the amount of force required to manipulate the introducer through the tissue [par. 0161]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the distal end portion as taught by Yoon by making it frustoconical as taught by Staskin in order to cam tissue out of the path of insertion and to reduce the amount of friction during insertion, thereby reducing the amount of force required to manipulate the introducer through the tissue. It is further noted that applicant's specification fails to provide any criticality and/or unexpected result associated with the claimed frustoconical distal end portion with a concave annular side wall. Therefore the examiner maintains that one of ordinary skill in the art would obviously recognize that any reasonable distal end portion shape may be used to achieve the desired results.

Response to Arguments

Applicant's arguments filed 9/15/09 with regards to Turkel have been fully considered but they are not persuasive. Applicant argues that Turkel fails to disclose the surgical instrument stretching the distal end portion of the instrument introducer. However, the examiner interprets

element 18 as disclosed by Turkel to also be part of the surgical instrument, and thus meets the claim limitations.

Newly applied reference Yoon (US 5752970) has been additionally cited to address applicant's claim amendments.

In response to applicant's arguments against the references of Yoon and Staskin individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA W. CHEN whose telephone number is (571)272-3356. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victoria W Chen/
Examiner, Art Unit 3739

/John P Leubecker/
Primary Examiner, AU 3739